DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Debra J. Rasmussen
Director of Regulatory Affairs
Veridex LLC.
1001 US Hwy 202
Raritan, NJ 08869

JAN 1 8 2005

Re: k040898
Trade/Device Name: CellSearch™ Epithelial Cell Control Kit
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: NRS
Dated: June 2, 2004
Received: June 3, 2004

Dear Ms. Rasmussen:

This letter corrects our substantially equivalent letter of June 28, 2004 regarding product code. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K040898

Device Name: CellSearch™ Epithelial Cell Control Kit

Indications for Use: The CellSearch™ Epithelial Cell Control kit is intended for use as an assayed control, when performing the CellSearch™ Epithelial Cell Kit on the CellTracks® AutoPrep System, to ensure that the sample detection and identification systems are working.
For *in vitro* diagnostic use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040898

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

2.3 510(k) Summary

JUN 2 8 2004

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K040898

2.3.1 Submitter Name, Address, Contact Information

Veridex, LLC
A Johnson and Johnson company
1001 US HWY 202
Raritan, New Jersey 08869-0606

Contact Person: Debra J. Rasmussen
Director, Regulatory Affairs
Veridex, LLC
Telephone: (908) 704-3942
Fax: (908) 704-3122
Email: drasmus1@vrxus.jnj.com

2.3.2 Preparation Date

Date 510(k) Summary Prepared: March 31, 2004

2.3.3 Device Name and Device Classification Information

Trade or Proprietary Name:	CellSearch™ Epithelial Cell Control Kit
Common or Usual Name:	Epithelial Cell Control, Hematology Quality Control Materials
Classification Name:	Control, Hematology Quality Control, Mixtures
Product Code:	NRS
Device Classification:	II
Classification Panel:	Hematology and Pathology Devices
Regulation Number:	21CFR 864.8625

2.3.4 Establishment Registration Number

Pending.

2.3.5 **Special Controls** under 513(b) and 514

No Special controls have been issued for *in vitro* devices under sections 513 and 514. Not applicable.

2.3.6 **Predicate Device**

The CellSearch™ Epithelial Cell Control Kit is substantially equivalent to the Control Cell Kit cleared with the CellSearch Epithelial Cell Kit/Cellspotter 510(k) #K031588.

2.3.7 **Device Description**

The CellSearch™ Epithelial Cell Control contains single-use vials of fixed cells from a breast carcinoma cell line (SKBR-3). Each vial contains two populations of cells for high and low level control. A CellSearch™ Epithelial Cell Control vial is substituted for a patient sample to verify the performance of the CellSearch™ Epithelial Cell Kit reagents (K031588), sample processing by the CellTracks® AutoPrep System (K040077), and cell analysis by the CellSpotter® Analyzer(K031588).

Each single use vial in the CellSearch™ Epithelial Cell Control Kit contains two populations of SKBR-3 cells at different concentrations (low and high). The two cell populations are distinguished from each other by use of fluorescent dyes that are specific for each population. This permits simultaneous enumeration of low and high control cell populations by the CellSpotter® Analyzer. The control cells are fully compatible with CellSearch™ Epithelial Cell Kit reagents and are magnetically captured by the CellSpotter® Analyzer and acquired as images that are displayed to the user for final classification. The cells are differentiated as control cells by the detection of fluorescence in the high or low control channels of the CellSpotter® Analyzer.

The CellSearch™ Epithelial Cell Control Kit contains 24 single-use bottles of CellSearch™ Epithelial Cell Controls. Each bottle contains 3.5 mL of two populations of fixed SKBR-3 cells (a human breast carcinoma derived cell line) in Histopaque® (Sigma Aldrich Trademark), 5% bovine serum albumin and 0.1% sodium azide.

The standard deviation is that which is anticipated for single determinations of the epithelial cell controls at the two levels (high and low) in a number of different laboratories using different reagent batches.

2.3.8 Device Intended Use

The CellSearch™ Epithelial Cell Control kit is intended for use as an assayed control, when performing the CellSearch™ Epithelial Cell Kit assay on the CellSpotter® Analyzer/CellTracks® AutoPrep System, to ensure that the sample detection and identification systems are working.

2.3.9 Summary Comparison to Predicate Device

The CellSearch™ Epithelial Cell Control Kit is substantially equivalent to the Control Cell Kit cleared with the CellSearch Epithelial Cell Kit/Cellspotter 510(k) #K031588 and does not raise any new questions regarding safety and effectiveness.

Table 2.1 lists the characteristics of the CellSearch™ Epithelial Cell Control Kit (new device) and the Control Cell Kit (predicate device).

Table 2.1. Summary Comparison of New Device and Predicate Device		
Device Characteristic	**CellSearch™ Epithelial Cell Control Kit (New device)**	**Control Cell Kit (Predicate device)**
Intended use	The CellSearch™ Epithelial Cell Control kit is intended for use as an assayed control, when performing the CellSearch™ Epithelial Cell Kit on the CellSpotter® Analyzer/CellTracks® AutoPrep System, to ensure that the sample detection and identification systems are working.	The Control Cell kit is for use as an assay control, when performing the CellSearch™ assay, to ensure that the sample detection and identification systems are working.
Cells	Breast cancer cell line (SKBr-3)	Same
Fixative	Paraformaldehyde	Same
Matrix of controls	**Histopaque 1083**, 5% Bovine Serum Albumin, 0.1% sodium azide	**Phosphate Buffered Saline**, 5% Bovine Serum Albumin, 0.1% sodium azide
Control Cell Levels; Expected Target values	**Two** populations of cells; High (1000 cells/test); **Low (50 cells/test)**	**One** (high) cell population, 1000 cells/test
Dyes used to pre-label cells	DiOC16(3) for high control cell population; **DiIC18(5) for low control cell population**.	DiOC16(3) for high control cell population.
Tests/vial	**Unit dose** (**one** test/vial); **24** tests per kit	**10** tests/vial; **10** tests per kit

Note: On **Table 2.1** the differences are **bolded.**

2.3.10 Summary of Assessment of Performance Data

Data are presented that demonstrate the use of the controls to assess the performance of the CellSearch™ Epithelial Cell Kit using the CellSpotter® Analyzer and CellTracks® AutoPrep System when detecting and enumerating circulating tumor cells (CTC) in whole blood. Included in this 510(k) submission is the performance data that describes the assessment done to verify the CellSearch™ Epithelial Cell Control function, demonstration that the Control Matrix is substantially equivalent to whole blood for the CellSearch Assay, and has acceptable precision. The assay results support that the controls can monitor that assay performance is working.